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APPLICATION NO.	FI	LING DATE	. FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,497	05/01/2001		Amina Odidi	9577-25 LAB	2340
	7590	05/15/2002			
Lola A. Bartoszewicz Sim & McBurney				EXAMINER	
6th Floor 330 Universit	·		PRYOR, ALTON NATHANIEL		
Toronto, ON			ART UNIT	PAPER NUMBER	
CANADA				1616	
·				DATE MAILED: 05/15/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

The separation

## Office Action Summary

Application No. 09/845,497

Applicant(s)

Odidi et al

Examiner

**Alton Pryor** 

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The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
	for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE $\_$ $3$ $\_$ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.						
	ions of time may be available under the provisions of 37 CFR 1.136 (a). In a date of this communication.	no event, however, ma	ay a reply b	e timely filed after SIX (6) MONTHS from the		
- If NO p - Failure - Any re	period for reply specified above is less than thirty (30) days, a reply within the period for reply is specified above, the maximum statutory period will apply a to reply within the set or extended period for reply will, by statute, cause the ply received by the Office later than three months after the mailing date of the patent term adjustment. See 37 CFR 1.704(b).	and will expire SIX (6) Notes that the specific action to become	MONTHS from ABANDO	om the mailing date of this communication NED (35 U.S.C. § 133).		
Status						
1) 🗆	Responsive to communication(s) filed on					
2a) 🗌	This action is <b>FINAL</b> . 2b) 💢 This act	ion is non-final.				
3) 🗆	Since this application is in condition for allowance eclosed in accordance with the practice under <i>Ex pai</i>					
-	tion of Claims					
4) 💢	Claim(s) 1, 6-9, 11, 15-17, and 21-33			is/are pending in the application.		
4	a) Of the above, claim(s)	·		is/are withdrawn from consideration.		
5) 💢	Claim(s) 1, 8, 9, 16, 26, and 31			is/are allowed.		
6) 💢	Claim(s) 15, 17, 21, 23-25, 28-30, 32, and 33			is/are rejected.		
7) 💢	Claim(s) 6, 7, 11, 22, and 27			is/are objected to.		
8) 🗆	Claims	are :	subject	to restriction and/or election requirement.		
Applica	tion Papers					
9) 🗆	The specification is objected to by the Examiner.					
10)	The drawing(s) filed on is/are	a) 🗆 accepted	or b)[	$\square$ objected to by the Examiner.		
	Applicant may not request that any objection to the d	rawing(s) be held	d in abey	vance. See 37 CFR 1.85(a).		
11)	The proposed drawing correction filed on	is:	a)□ a	pproved b) $\square$ disapproved by the Examiner		
	If approved, corrected drawings are required in reply t	to this Office acti	ion.			
12)	The oath or declaration is objected to by the Exami	ner.				
	under 35 U.S.C. §§ 119 and 120					
	Acknowledgement is made of a claim for foreign pr	riority under 35	U.S.C.	§ 119(a)-(d) or (f).		
a) [	All b)□ Some* c)□ None of:					
	1. $\square$ Certified copies of the priority documents hav					
	2. U Certified copies of the priority documents hav	e been received	in App	lication No		
	3. Copies of the certified copies of the priority do application from the International Bures	au (PCT Rule 17	7.2(a)}.	_		
_	ee the attached detailed Office action for a list of the					
	Acknowledgement is made of a claim for domestic					
a) The translation of the foreign language provisional application has been received.  15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachme		priority under 3	0.5.0	2. 99 120 and/or 121.		
	errus) tice of References Cited (PTO-892)	4) Interview Sum	mary (PTO	-413) Paper No(s).		
	tice of Draftsperson's Patent Drawing Review (PTO-948)			Application (PTO-152)		
	ormation Disclosure Statement(s) (PTO-1449) Paper No(s)	6) Other:		•		

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In the present instance, claim 15 recites the broad recitation sulfonylureas, and the claim also recites including glyburide, etc. which is the narrower statement of the range/limitation.

Regarding claims 24,25,28,29, the term "type" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

4. Claim 32 recites the limitation "0 % compression aid" and "0% extrusion aid" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

### Claim Rejection under 35 U.S.C. 103(a)

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 17,21,23,30,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (US 6,099,859; 8/8/00). Cheng teaches a extended time release formulation comprising an antihyperglycemic drug. The drug is formulated into a tablet which is encased in a semi-permeable membrane (polymer film). The polymer membrane is soluble at pH 7.5. Cheng teaches that the membrane is made of methacrylic acid copolymer comprising PEG, plasticiziers, and excipients. Cheng also teaches that the time release period of antihyperglycemic drug is from 12-24 hours. See column 2 lines 16-43, column 3 line 30 column 5, claim 17. Cheng does not

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teach the formulation comprising the instant amounts of PEG. However, one having ordinary skill in the art would have been expected to determine the optimum amounts through routine experimentation. One would have been motivated to do this in order to make a a formulation that would have the proper time release characteristic. In reference to the making of the instant invention, it is well known to compress active ingredients into tablets and to follow with the encasement of the tablet.

### Claim Objection / Allowable Subject Matter

Claims 11,22,27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not suggest a time release tablet of the instant claims comprising shellac or zein. Claims 1,8,9,16,26,31 are allowable. The prior art does not teach or suggest the instant invention comprising the instant group of compression aids.

#### Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Alton Pryor

Primary Examiner, AU 1616

3/28/03